

News from Ed Markey

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CONSPIRACY OF SILENCE: FDA ALLOWS DRUG COMPANIES TO ABUSE THE “ACCELERATED APPROVAL” PROCESS, COMPANIES FAIL TO CONDUCT FOLLOW-UP STUDIES

New Markey report exposes that FDA/drug companies keep patients and investors in the dark

Washington, DC: Representative Edward J. Markey (D-MA), a Senior Member of the Energy and Commerce Committee, today will release a staff report: *Conspiracy of Silence: How the FDA Allows Drug Companies to Abuse the Accelerated Approval Process*. The report reveals that the majority of pharmaceutical companies benefiting from the Food and Drug Administration (FDA)’s “accelerated approval” process, a mechanism designed to expedite drugs for patients with life-threatening illnesses, have not conducted the post-marketing studies that are required by law on a timely basis. The report also details information provided by the Security and Exchange Commission (SEC) indicating that many drug companies have not disclosed information regarding postmarketing studies to their investors. Of the 91 postmarketing studies required by the FDA, 42 studies have not been completed and half of the unfinished studies have not even started.

“It is outrageous that drug companies and the FDA have been dragging their feet when it comes to conducting required postmarketing studies. Pharmaceutical products approved under the accelerated approval process are designed to treat patients with life threatening illnesses, so ensuring the effectiveness of these drugs is a life or death matter for many patients,” said Representative Markey.

The importance of post-marketing studies is highlighted by the recent case of the drug Iressa which was approved by the FDA in 2003 under the “accelerated approval” process for treatment of non-small cell lung cancer. In early studies Iressa caused significant shrinkage in tumors in about 10% of patients and was expedited to the market. AstraZeneca, the company producing Iressa, complied with the FDA and conducted a follow up study of approximately 1700 patients. The study revealed that the cancer therapy showed no survival benefit in comparison to a placebo. The FDA shared the outcome of the study with the public and suggested alternative treatments. The FDA’s announcement of the AstraZeneca’s important trial prevented patients from spending \$1,800 a month for a drug that is ineffective when there are alternative treatments available. The Markey report raises concerns that other companies who have failed to carry out similar commitments could have similar problems.

“It is very important that those drugs that hold the promise of helping to save lives and reduce pain and illness get to patients quickly. But this expedited approval process is done under the condition that a full review of their safety and effectiveness will be a priority for the drug company and the FDA. After all, a drug tested on a few thousand people for a few months cannot be assumed to be safe for millions of people to use over the years to come. The data in Markey’s report is further evidence of the need for this Congress to make major reforms in the FDA’s post market approval safety system,” Senior Policy Analyst Bill Vaughan, Consumers Union.

The Markey Report also reveals that pharmaceutical company shareholders may not know about a company’s postmarketing study commitments. According to information provided by the SEC, 68% of public companies have not disclosed any of their post-marketing study commitments to their shareholders in their filings with the SEC.

“Not only have the American people been left in the dark about their gamble when taking these drugs, but investors may have been left in the dark about what the drug companies have been doing – or failing to do,” Rep. Markey said.

“This report exposes failures on two fronts. Some pharmaceutical companies may have failed to protect their consumers and their shareholders. In turn, the FDA, which is supposed to be the watchdog of the drug industry, hasn’t required companies to adhere to FDA policies on post-marketing testing. I will be proposing legislation to address the failures of the drug companies and the FDA to do their due diligence in order to protect patients and doctors across the country. My bill will require that companies inform patients and physicians when a product has received conditional approval under this “accelerated approval” system. The legislation will also clarify the law to ensure the FDA has full authority to require further postmarketing studies after a product is already on the market. I want to make sure that we put the needs of patients and doctors first, expediting information to the public about these critical treatments,” Rep. Markey.

Rep. Markey, author of legislation to create a federal registry of all clinical trials – to ensure that pharmaceutical companies disclose the results of all clinical trials, will introduce new legislation next week aimed at providing information to patients and doctors about “accelerated approval” process drugs and improving the capacity of the FDA to oversee the postmarketing studies.

The Markey legislation will:

- ◆ Require that companies inform patients and physicians when a product has received conditional approval under the accelerated approval system.
- ◆ Require that companies distinguish between a conventional approval and an accelerated approval with conditions on the product’s label.
- ◆ Shift the risk-reward analysis in favor of doing the promised studies with
 - Civil monetary penalties for failure to conduct studies with due diligence.
 - Enhanced penalties associated with any harm that occurs to a consumer because a post-marketing study was never undertaken or not completed in a timely manner.
- ◆ Clarify in statute that the FDA has the authority to require further postmarketing studies after a product is already on the market.
- ◆ Clarify in statute that the FDA has the power to make a change on a product’s label.

- ◆ Ensure that whistleblowers at the FDA have adequate protections.

For more information on Rep. Markey's legislation and the letters provided to Rep. Markey by the FDA and Securities and Exchange Commission (SEC) which have provided the evidence for this report check out: <http://www.house.gov/markey/>